

REMARKS/ARGUMENTS

After entry of this amendment, claims 17, 18, 29, 31, 32, and 72-74 are pending in the present application. New claims 72-74 are directed to exemplified embodiments of the invention. Support for claim 72 is found, for example, in Table 1 on page 19 of the application. Claims 73 and 74 find support on page 19, lines 9-11.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 28 and 30 remain rejected for allegedly being indefinite. Without necessarily acceding to the rejection, Applicants have cancelled these claims to expedite prosecution. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 13-18, 28-32 and 69-71 remain rejected for allegedly lacking enablement for allegedly encompassing compositions comprising nonfunctional AAT. To expedite prosecution, Applicants have amended the claims to explicitly recite that the AAT in the claimed compositions is a functional serine protease inhibitor, which the Examiner acknowledges as enabled in the Office Action. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

The rejection of claims 13-18, 28-32 and 69-71 for allegedly being obvious over US Patent No. 5,618,786 and US Patent No. 6,267,958 in view of US Patent No. 6,653,284 and US Patent No. 5,166,134 is respectfully traversed.

The present rejection is essentially identical to the obviousness rejection made in the Office Action mailed August 27, 2009. The Examiner continues to cite a collection of prior art references that each disclose some, but not all, of the components of the claimed compositions. Based on these disclosures, the Examiner simply asserts that the particular claimed compositions are *prima facie* obvious with out articulating any reasoning or providing any evidence to show why one of skill would be led to the claimed invention based on these disclosures. Applicants have previously presented arguments to show that the Examiner has failed to establish a proper case of *prima facie* obviousness.

It is well settled that the Examiner must also consider evidence of surprising or unexpected results of the claimed invention. MPEP §2145. To expedite prosecution, the pending claims are now directed to compositions of the invention that have been shown to be surprisingly effective in maintaining stability of the AAT at a variety of temperatures.

As explained in the paragraph bridging pages 13 and 14 of the specification, a number of AAT formulations were tested for stability for up to 6 months at -70°C, 5°C, 25°C, 40°C, 50°C, and 60°C (*see* Table 2, pages 20-21). Four excipients were included in the formulations: 1) protein stabilizer (trehalose, 0% to 5%), 2) surfactant (Tween-80, 0.0 % to 0.5%), 3) antioxidant (methionine, 5mM), and 4) buffering agent (sodium phosphate, 1mM). The formulations were evaluated by conducting assays for functional activity, total protein and aggregation (i.e., % monomer).

As explained on pages 18-19, the nine formulations tested all showed significant improvements in stability relative to AAT compositions without stabilizers. Inclusion of trehalose had the most appreciable beneficial effect on stability of the various factors tested (*see* Table 3, pages 22-23).

The results presented here establish the surprising effectiveness of the claimed compositions to maintain stability of AAT for up to 6 months, at a variety of temperatures. The data show that trehalose is particularly effective in maintaining stability of AAT in the formulations. None of the cited references disclosed or suggest the surprising effectiveness of the claimed compositions, as presently claimed. In view of the surprising properties of the present invention, withdrawal of the rejection is respectfully requested.

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PATENT

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,

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